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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/656,973
Filing Date: September 05, 2003
Appellant(s): ROSENBERG, MEIR

Christina M. Sperry
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4 November 2008 appealing from the Office action mailed 4 June 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,533,733	Ericson	03-2003
2003/0004495	SAUL	01-2003
2003/0032915	SAUL	02-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6, 7, 9, 13-15, and 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0032915 A1 to Saul in view of US 6,533,733 to Ericson et al.

In the specification and figures, Saul discloses the invention substantially as claimed by Appellant. With regard to claims 1, 9, 17, Saul discloses a method and device for volumetric removal of CSF from a hydrocephalus patient with an implantable, controllable shunt system. Saul discloses a ventricular catheter 12 and peritoneal catheter 14 that are connected via a flow control valve 48. The catheters operate to shunt CSF from the brain ventricle to the peritoneal cavity (see paragraph 0034). The system is operated via controller 44 that operates the movement of the valve 48 with power from source 46 based on input from a sensor such as a pressure transducer 40

that is located on the distal end of catheter 12, within the ventricle (see paragraph 0034).

Saul fails to disclose that an external system controller communicates with the shunt and valve system remotely via telemetry. However, Ericson discloses a method and device for monitoring and shunting cerebrospinal fluid that comprises a transmitter 15 implanted within the patient that communicates with receiving unit 44 of an external telemetry system to enable remote manual energizing, monitoring, and control of the implant (see column 3, lines 5-10, 35-38, 65-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add an external controller that communicates via telemetry as disclosed by Ericson to the cerebrospinal shunt system disclosed by Saul in order to enable remote monitoring and control, as taught by Ericson. Furthermore, all the elements of the apparatus and steps of the method are suggested by the prior art. One of ordinary skill in the art could have combined the claimed elements by known methods to yield the predictable result of a CSF shunt system that uses a remote monitoring system to adjust valve resistance based on ventricular pressure measurements, as suggested by the prior art. Accordingly, it is the position of the Examiner that the instantly claimed invention is not patentable over the cited prior art.

With regard to claims 2-4, 6, 7, 19-23, Saul discloses that when CSF fluid drainage is being controlled by volume, sensing devices in the shunt (such as pressure sensor 40) send signals to the controller 44, which adjusts the valve between an open and closed position based on the signals sent to the controller from the sensor (see

paragraphs 0035-0037). The sensor reports the volume of flow through the valve, and once the desired volume has been reached (which the controller must determine by comparing the measured value to a desired value), the controller sends an electrical control signal to the valve, adjusting the resistance of the valve to open (decreased resistance) or closed (increased resistance) in order to continue or halt fluid flow (see paragraphs 0035-0037).

With regard to claims 13-15, Saul specifically discloses that his apparatus and method are particularly intended for patients who experience hydrocephalus with "normal" intracranial pressures, i.e, normal pressure hydrocephalus (see paragraph 009).

With regard to claim 18, sensor 40 is coupled to controller 44, which is coupled to valve 48, meeting the limitations of the claim.

With regard to claims 24-25, Ericson discloses that the sensors 11 of the shunt may comprise multiple pressure transducers (see column 3, lines 40-43). Therefore, it would have been obvious to one having ordinary skill in the art to provide multiple sensors as disclosed by Ericson, since it has been held that the mere duplication of the essential working parts of a device found in the prior art involves only routine skill in the art. See MPEP 2144.04(VI)(B).

With regard to claim 26, Saul fails to disclose that the valve is configured for implantation in the peritoneal cavity of the patient. Absent any showing of new or unexpected results of such a change in the location of the valve, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

place the valve in the peritoneal cavity, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

Claims 5, 8, 16, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0032915 A1 to Saul in view of US 6,533,733 to Ericson, further in view of US 2003/0004495 A1 to Saul.

In the specification and figures, Saul '915 and Ericson disclose the method substantially as claimed by Appellant with the exception of repeating the resistance adjustment procedure at proscribed time intervals.

Saul '495 discloses a method and device for treating normal pressure hydrocephalus that comprises the steps of sensing a patient parameter, and then adjusting the opening pressure of a shunt valve with a controller based on patient conditions (see paragraphs 0019-0027).

With regard to claims 5, 8, and 16, the procedure disclosed by Saul '495 may be repeated, if desired, a set number of times per day, with the time between treatments set to allow the CSF to drain from a reservoir, allowing the patient to adjust to the current resistance of the valve, until a total desired volume of CSF is removed from the ventricular space, in order to prevent CSF leakage (see paragraph 27).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to repeat the adjustment procedure suggested by Saul '915 and Ericson multiple times, as disclosed by Saul '495, in order to prevent CSF leakage, as taught by Saul '495.

With regard to claim 27, the prior art discloses the device as claimed with the exception of a timed shut-off mechanism. Saul 495 discloses that his device may be controlled by a timer or programmable controller in order to control the valve based on a predetermined time schedule in order to prevent overdrainage of CSF from the patient during a single time period (see paragraph 0027). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an automatic shutoff to the CSF shunt system in order to prevent overdrainage of CSF from a patient during a particular time period.

(10) Response to Argument

Appellant argues that these is no reason a person of ordinary skill in the art would combine Saul and Ericson because there is no advantage to the proposed modification, since Saul 915 already provides for adjusting valve pressure and resistance. However, it is the position of the Examiner that the advantage derived from combining the teachings of Saul with Ericson is not the mere adjustment of valve pressure and resistance, but the ability to *remotely* adjust the valve pressure and resistance without the need for adjusting associated wires and sensors, as taught by Ericson. As such, there is, in fact, a recognized advantage to the combination of Saul 915 and Ericson as proposed by the Examiner.

Appellant argues that the mere presence of claim elements existing in the prior art do not establish obviousness. The Examiner agrees that in addition to the existence of the claimed element, there should be a rational reason why one of ordinary skill in the

art would combine the known elements. Appellant further argues that the references must be considered as a whole and "must suggest the desirability" of the claimed combination. MPEP § 2141(II)(B). The Examiner respectfully disagrees. In an obviousness analysis, it is not necessary to find precise teachings in the prior art directed to the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). A basis to combine teachings need not be expressly stated in any prior art reference. *In re Kahn*, 441 F.3d 977, 989 (Fed. Cir. 2006). There need only be an articulated reasoning with rational underpinnings to support a motivation to combine teachings. *In re Kahn*, 441 F.3d at 988. In the instant case, Saul 915 discloses a method and device for removing CSF from a patient comprising the claimed shunt and adjustable valve elements. Ericson discloses an implantable method and device for removing CSF from a patient with a shunt and valve element that is adjustable outside the immediate vicinity of the patient. One of ordinary skill in the art at the time of invention could have combined the elements disclosed by Saul 915 and Ericson to yield an apparatus for draining CSF from a patient with a remotely adjustable valve in order to allow adjustment without repeated trips to a care provider or reattachment of wires. Such an advantage comprises a rational reason for the proposed combination absent an express teaching in either of the references.

Appellant argues that the instantly claimed invention is a unique configuration that allows for CSF flow management of a patient with normal pressure hydrocephalus

that characterized by fluctuations in ventricular volume. However. the Examiner notes that the claimed method and apparatus does not recite any measurement of change in ventricular size, only a "characteristic," which may include pressure. Since Saul '915 discloses that ventricular pressure may be measured in the disclosed apparatus, and Ericson discloses a shunt that uses telemetric communication, it is the position of the Examiner that the instantly claimed invention is unpatentable over the suggestion of the prior art.

Appellant argues that the Examiner's obviousness analysis is incomplete because it emphasizes the teachings and suggestions of the prior art and does not address Appellant's argument that the combination of Saul 915 and Ericson renders the Saul 915 apparatus inoperable. The Examiner has, in fact, addressed those arguments in the Final Rejection and again below.

Appellant argues that modifying Saul 915 in view of Ericson changes the principle of operation of Saul 915 because unlike the Saul 915 apparatus, the Ericson apparatus does not continuously and automatically monitor a patient's intracranial pressure. However, Saul 915 does not necessarily require "continuous" monitoring. In the passage quoted by Appellant, Saul specifically discloses that the monitoring can be performed "frequently," which Saul 915 distinguishes from "continuously." (See Saul 915, paragraph 0010.) Furthermore, Appellant points to no disclosure in Ericson that specifically prevents or teaches away from frequent, or even continuous, monitoring. Ericson discloses that the controller "periodically" transmits operation date from the shunt to a receiver 44, but does not define the interval. (See Ericson paragraph 5, lines

21-30). It is the position of the Examiner that absent any disclosure or teaching that Ericson's "periodic" monitoring differs substantially from Saul 915's "frequent" monitoring, the Ericson communication apparatus is capable of performing in the time intervals required by Saul 915. Accordingly, it is the position of the Examiner that the proposed combination does change the principle of operation of the Saul 915 device.

Appellant argues that modifying Saul 915 in view of Ericson would require a substantial redesign of Saul 915 because manually energizing the Saul 915 apparatus would require removal of the existing controller and replacement with a manually energizable controller. However, Saul 915 specifically discloses that in one embodiment, data regarding the operation of the shunt apparatus may be transmitted to an external sensor when the device is externally recharged. (See Saul 915 paragraph 0036.) Such a disclosure indicates that the controller disclosed by Saul 915 is capable of responding to external commands (such as a command to transmit data) that is created by "manually energizing" the implant by recharging the apparatus. Since Saul 915 suggests a connection with an external device during a recharging event, it is the position of the Examiner that combining Saul 915 with Ericson does not require a substantial redesign of the Saul 915 device.

Appellant argues that modifying Saul 915 in view of Ericson renders Saul 915 unsatisfactory for its intended purpose because Saul 915 is directed to continuously monitoring a patient's intracranial pressure and automatically opening or closing a valve to maintain a target pressure. However, as pointed out above, Saul does not, in fact, require "continuous" monitoring, only "frequent" monitoring, which may be accomplished

if combined with the teachings of Ericson. Furthermore, the Appellant has failed cite, nor can the Examiner locate, anywhere in the Saul 915 disclosure that references "automatic" valve opening and closing. As such, it is the position of the Examiner that modifying Saul 915 in view of Ericson does not render Saul 915 unsatisfactory for its intended purpose, since Saul 915 does not specifically provide for exclusive "continuous" and "automatic" monitoring and adjustment, as alleged by Appellant.

Appellant argues that providing an manual means to replace an automatic activity is not inherently obvious. The Examiner agrees, and is not asserting that such a replacement in the instant case is, in fact, inherently obvious. Rather, the Examiner notes that since Saul 915 discloses a) "frequent" monitoring, and b) the ability to manually prompt transmission of data to an external sensor, that *in this case*, using a telemetry system to manually adjust the operation of an implanted valve is an obvious variation of using an internal controller to accomplish the same purpose.

Appellant argues that claim 22 is patentable over Saul 915 in view of Ericson. The Examiner notes that claim 22 is drawn to an apparatus, and not a method. In claim 22, Appellant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. As such, since the prior art apparatus is capable of being programmed to operate with a target pressure, it is necessarily capable of operating with a target pressure obtained through the steps claimed by Appellant.

Appellant argues that Saul 495 fails to cure the deficiencies of the combination of Saul 915 with Ericson, but does not argue each rejection individually. Accordingly, it is the position of the Examiner that the Saul 495 reference fairly teaches the elements and steps for which it was cited.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Leslie R. Deak/

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